PATENT COOPERATION TI ΛTY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissi ner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 21 March 2000 (21.03.00)	
International application No. PCT/GB99/02510	**Applicant's or agent's file reference** SPG/P36001WO
International filing date (day/month/year) 30 July 1999 (30.07.99)	**Priority date** (day/month/year) 13 August 1998 (13.08.98)
Applicant PARKER, Dawood	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   07 March 2000 (07.03.00)

   [ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland** Facsimile No.: (41-22) 740.14.35	Authorized officer V. Gross Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

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NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

GILHOLM, Steve
Harrison Goddard Foote
Tower House
Merrion Way
Leeds LS2 8PA
ROYAUME-UNI

Date of mailing (day/month/year) 27 July 2000 (27.07.00)	
Applicant's or agent's file reference SPG/P36001WO	**IMPORTANT NOTIFICATION**
International application No. PCT/GB99/02510	**International filing date** (day/month/year) 30 July 1999 (30.07.99)

1. The following indications appeared on record concerning:

☐ the applicant ☐ the inventor ☒ the agent ☐ the common representative

Name and Address	State of Nationality	State of Residence
GILHOLM, Steve Harrison Goddard Foote Belmont House 20 Wood Lane Leeds LS6 2AE United Kingdom		
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	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address	State of Nationality	State of Residence
GILHOLM, Steve Harrison Goddard Foote Tower House Merrion Way Leeds LS2 8PA United Kingdom		
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	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
☐ the International Searching Authority
☒ the International Preliminary Examining Authority
☐ the designated Offices concerned
☒ the elected Offices concerned
☐ other:

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland** Facsimile No.: (41-22) 740.14.35	Authorized officer A. Karkachi Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference SPG/P36001WO	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 99/02510	International filing date *(day/month/year)* 30/07/1999	(Earliest) Priority Date *(day/month/year)* 13/08/1998
Applicant WHITLAND RESEARCH LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.
   [ ] filed together with the international application in computer readable form.
   [ ] furnished subsequently to this Authority in written form.
   [ ] furnished subsequently to this Authority in computer readble form.
   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [X] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [ ] the text is approved as submitted by the applicant.
   [X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 5

   [ ] as suggested by the applicant.
   [ ] because the applicant failed to suggest a figure.
   [X] because this figure better characterizes the invention.
   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 99/02510

B x I Observations wher certain claims wer found unsearchabl (Continuation f item 1 of first sh et)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 29-30
   because they relate to subject matter not required to be searched by this Authority, namely:
   Rule 39.1 (iv) PCT - Program for computers

2. [ ] Claims Nos.:
   because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

B x II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

   1-17,32

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-17, 32

   A sensor device for measuring blood oxygen saturation.

2. Claims: 18-27

   A method of monitoring arterial blood oxygen saturation comprising measuring blood oxygen saturation and adding a scaling factor.

3. Claim : 28

   A data collection, processing and display system.

4. Claim : 31

   A sensor device programmed with a computer programme adapted for absorption data collection, processing and display of blood oxygen saturation and arterial blood oxygen saturation levels.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

A sensor device (1) which comprises light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength of light received by the photodetector means characterised in that the sensor device measures blood oxygen saturation. The device can be used in conjunction with a conventional pulse oximeter.
There is also described a method of measuring blood oxygen saturation.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 99/02510

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 03102 A (UNIVERSITY COLLEGE OF SWANSEA ET AL) 17 February 1994 (1994-02-17) cited in the application page 1, line 28 -page 3, line 8 abstract	1,2,5,6, 15,17,32
X	US 3 638 640 A (R. F. SHAW) 1 February 1972 (1972-02-01)	1,2,5,6, 15,32
A	column 2, line 30 -column 3, line 50	7,16,17
X	EP 0 286 142 A (SUMITOMO ELECTRIC INDUSTRIES, LIMITED) 12 October 1988 (1988-10-12)	1,2,5,6, 15,32
Y	page 2, line 13 -page 4, line 4	3,4,7,8

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 November 1999	22.02.2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Geffen, N

1

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 586 025 A (M. R. ROBINSON ET AL) 9 March 1994 (1994-03-09)	1,2,5,6, 15,32
Y	page 4, line 32 - line 54 page 10, line 48 -page 13, line 15	3,4,7,8
A		9-14,17

Y	WO 91 01678 A (NATIONAL RESEARCH DEVELOPMENT CORPORATION) 21 February 1991 (1991-02-21)	3,4
A	page 3, line 6 -page 5, line 4	1,2,5,6, 11-13,32

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 99/02510

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9403102 A	17-02-1994	AU 4719893 A	03-03-1994
		ZA 9305579 A	02-02-1994
US 3638640 A	01-02-1972	DE 2049716 A	13-04-1972
EP 0286142 A	12-10-1988	JP 63252239 A	19-10-1988
		DE 3851251 D	06-10-1994
		DE 3851251 T	15-12-1994
		US 4867557 A	19-09-1989
EP 0586025 A	09-03-1994	US 5355880 A	18-10-1994
		CA 2099400 A	07-01-1994
		JP 6178767 A	28-06-1994
		US 5630413 A	20-05-1997
		US 5792050 A	11-08-1998
WO 9101678 A	21-02-1991	EP 0484442 A	13-05-1992
		GB 2235288 A,B	27-02-1991
		JP 5504266 T	08-07-1993

PCT WORLD INTELLECTUAL PROPERTY ORGANIZ
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(30) Priority Data:
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9904232.7 25 February 1999 (25.02.99) GB

(71) Applicant (*for all designated States except US*): WHITLAND RESEARCH LIMITED [GB/GB]; Whitland Abbey, Whitland, Dyfed SA34 0LG (GB).

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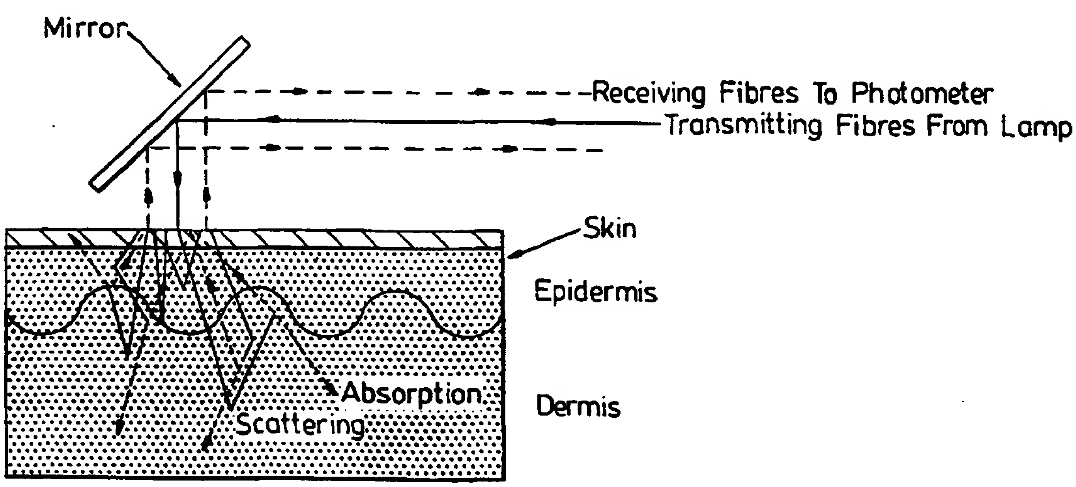
(75) Inventor/Applicant (*for US only*): PARKER, Dawood [GB/GB]; Whitland Abbey, Whitland, Dyfed SA34 0LG (GB).

(74) Agent: GILHOLM, Steve; Harrison Goddard Foote, Belmont House, 20 Wood Lane, Leeds LS6 2AE (GB).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: OPTICAL DEVICE



(57) Abstract

There is described a sensor device which comprises light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength of light received by the photodetector means characterised in that the sensor device measures blood oxygen saturation. The device can be used in conjunction with a conventional pulse oximeter. There is also described a method of measuring blood oxygen saturation.

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OPTICAL DEVICE

This invention relates to an optical device for monitoring or measuring/displaying the arterial oxygen saturation with motion artefact suppression and to a novel medical technique for providing arterial oxygen saturation data.

Monitors are available which use non-invasive optical techniques to measure the arterial oxygen saturation in patients. For example, it is known, that in order to measure blood oxygen saturation, it is necessary to provide a device which passes light through biological tissue, such as the human finger, and to monitor the transmitted or reflected output signal from a photodetector of this device continuously. Such devices are described, inter alia, in International Patent Application No WO94/03102.

As is well known in the art, these instruments suffer interference due to patient movement, i.e. motion artefact.

Movement of the subject leads to a change in the length of the path of the light through the biological tissue and hence to a variation in the intensity of light received by the photodetector. This renders the device incapable of distinguishing between changes in received light intensity caused by variations in light absorption by the component being monitored (eg oxygen in the blood), and changes in received light intensity caused by variations in the light pathlength due to movement of the subject. The problem is common to all optical monitoring devices and can render these devices inoperative for long periods of time. The problem is particularly severe in critical health care applications, were continuous monitoring is essential.

The device described in WO 94/03102 attempts to address the problem of the motion artefact in measuring SaO_2 by using an additional wavelength to enable the motion artefact to be cancelled. Although WO 94/03102 broadly describes the use of a plurality of wavelengths (including the n+1 motion artefact wavelength) the device

exemplified uses three wavelengths, namely, a pulse rate wavelength, an SaO_2 wavelength and a motion artefact wavelength. However, in practice, the three wavelengths proposed in WO 94/03102 are not sufficient to overcome motion sensitivity.

Generally, medical practitioners desire to measure arterial oxygen saturation (SaO_2). For example, conventionally used pulse oximeters measure SaO_2. We have now devised an optical measuring or monitoring device which is able to monitor or measure blood oxygen saturation (SO_2) and display the arterial blood oxygen saturation non-invasively and to suppress the effects of motion artefact.

Furthermore, existing optical devices do not take into account the variations in transmitted light with varying skin colours. Melanin is present in increasing concentrations from fair through brown to black skin. The peak of its absorption spectrum is at 500nm decreasing almost linearly with increasing wavelength. Melanin is present in the epidermis, thus, in very high concentrations as is the case in black skin, it can mask the absorption of haemoglobin in the dermis. Even in brown skin, the absorption by melanin is superimposed on that of haemoglobin so that any algorithm which uses the shape of the absorption spectrum in order to produce SO_2 value needs to compensate for this fact.

Thus, we have also devised an optical measuring or monitoring device which is capable of compensating for variations in melanin levels in the skin.

In accordance with this invention, there is provided a sensor device which comprises light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength of light received by the photodetector means characterised in that the sensor device measures blood oxygen saturation.

The sensor of the invention may use a spectral wavelength of from 526 to 586 nm.

In a preferred embodiment of the invention the light beam will emit a plurality of wavelengths, the arrangement being such that the signal levels corresponding to the different wavelengths bear a predetermined relationship with each other. A particular advantage of the sensor of the invention is that it only enables a user to compare "slopes" on a graph and the use of a range of different wavelengths allows for a more accurate determination without an increase in costs. In a preferred embodiment of the invention 3 or more different wavelengths are used, the optimum number of wavelengths is 5 or 6 and preferably 6.

It is also an important feature of the present invention that at least one or more of the wavelengths used are isobestic wavelengths. For the sake of clarity, by the term isobestic wavelength we mean a wavelength at which oxygenated haemoglobin and deoxygenated haemoglobin absorb the same amount of light. In a preferred embodiment substantially most of the wavelengths used are isobestic wavelengths. When six wavelengths are used it is preferred that five of them are isobestic wavelengths. In this preferred embodiment the sixth wavelength is one at which there is maximum difference between the absorption of light of oxygenated haemoglobin and deoxygenated haemoglobin.

Generally the device and technique of the present invention measures oxygen saturation (SO_2) ie the value of oxygen saturation in venous and arterial tissue combined. Because oxygen saturation in venous tissue is usually low it is well known that the value of SO_2 is less than that of SaO_2. In the technique of the invention we call the difference the scaling factor Δ, such that

$$SaO_2 - SO_2 = \Delta$$

Thus the technique of the invention initially measures SaO_2 using a conventional arterial blood oxygen meter eg a pulse oximeter. SO_2 is then measured to determine

and thus subsequently SO_2 measurements made using the device of the invention are corrected by the value of Δ. Furthermore, the device and technique of the invention continually, although intermittently, allows SaO_2 and thereby Δ to be checked.

The sensor device of the invention is generally an optical measuring or monitoring device.

The sensor may be attached to the chest or abdomen of an infant. The tip of the sensor may incorporate a mirror and is provided with an optical fibre light transmitting cable such that the fibre cable lies flat on the surface of the skin. White light (20 to 50W quartz halogen light bulb) is preferred and is transmitted along an optical fibre to the skin where multiple scattering occurs as photons interact with cellular and subcellular particles. Light can be absorbed by the haemoglobin present in the blood flowing in the tissue below the sensor before being scattered back along receiving optical fibres. The scattered light can be transmitted along a plurality eg in the preferred embodiment 6 separate fibres to 6 photodetectors via narrow-band optical filters all in the range 500 to 600nm (green/yellow visible light) and especially between 526 and 586. Generally, the number of detectors should be the same as the number of transmitting fibres. The sensor may optionally be heated above normal body temperature, to eg 40°C and up to 42°C for short periods the temperature may even reach 44°C. Alternatively, a single fibre of from 50 to 150nm in diameter may be used with one to three white LEDs.

Although the sensor of the invention may be adapted to operate with either transmitted light or reflected light, it is preferred that it operates on reflectance (remittance). Thus in contrast to, eg a pulse oximeter the transmitters and the sensors are situated on the same side of the tissue when in use.

According to a further feature of the invention we provide a "hand held" sensor device as hereinbefore described.

In particular, in the "hand held" sensor of the invention the optical fibre transmitting cable(s) may be replaced by a light emitting diode (LED) which significantly reduces the complexity of the sensor.

Before use, the sensor is normalised against darkness and a standard white surface, and the signal from each photodiode is measured to obtain the overall dark and "white balance" figures. Signal processing includes averaging for a period between 10 milliseconds to 10 seconds, subtracting the white balance signal, and taking a logarithm to produce a transmittance at each wavelength.

In the preferred embodiments, the use of 6 wavelengths gives the technique a considerable advantage over the pulse oximetry method which uses the minimum number of wavelengths necessary to obtain the information required. The use of more wavelengths in our method gives the technique stability against spurious disturbances at a particular wavelength, enables flexibility in the algorithm to cope with factors such as skin colour. Nevertheless, the sensor of the invention can utilise either oximetry or pulsed oximetry.

Averaging of the signal over a second or more also removes motion artefacts. It is also the case that the technique operates in the visible wavelength range. Thus, although the penetration of light into tissue is much less, the influence of poor contact with the tissue may also be considerably less thus reducing movement artefact. It is important to emphasis that our technique does not measure pulsatility as in the case in pulse oximetry.

SO_2 is the ratio of the oxyhaemoglobin concentration $[HbO_2]$ to the total concentration of haemoglobin ($[HbO_2]$ + [Hb], where [Hb] is haemoglobin concentration) expressed as a percentage.

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]}$$

SaO_2 is arterial oxygen saturation

The reflected absorptions (A) at six wavelengths (500, 528, 550, 560, 572 and 586 nm) are used to calculate two parameters HbI and OXI:

$$HbI = (A_{528} - A_{520}) + (A_{550} - A_{528}) + (A_{572} - A_{550}) - (A_{586} - A_{572})$$
$$OXI = ((A_{550} - A_{50}O) + (A_{572} - A_{560})) / HbI$$

SO_2 is calculated from the formula:

$$SO_2 = 100 = (OXI - OXI_o) / (OXI_{100} - OXI_o)$$

Where OXI_o and OXI_{100} are empirically determined values for OXI at SO_2 values of 0% and 100% in skin. HbI is the haemoglobin index such that

$$HbI \times k = [Hb]$$

where k is a constant.

The spectral range used for the algorithm is from 526 to 586nm and 22 absorption values are recorded within that range. The first process is to carry out a Kubelka and Monk transformation which reduces the intrinsic effect of the scattering of light within the skin.

The following operation is carried out:

$$\text{K-B Transformed spectrum} = 0.5 \times (R^2)/(1\text{-}R)$$

where R is the remitted spectrum (Reference: Kubelka, P and Munk F, Ein eitrag zur Optik der Farbanstriche, Zeitschrift fur technische Physik, 11a:593-601 (1931)).

In a paper presented by Wolfgang Dümmler in 1988, he describes that, according to the Kubelka-Munk theory (see Section II.2), the remission of an infinitely thick sample is dependent only on the quotients of absorption and scattering coefficients and is given by:

$$R_\infty = A/S + 1 - \sqrt{\{A/S\,(A/S + 2)\}}$$

The equation can be solved explicitly according to A/S

$$A/S = 0.5\,(R_\infty + 1/R_\infty) - 1$$

where R is the remitted spectrum that is the spectrum of light scattered back from the skin.

The transformed spectra are then "straightened" by subtracting the interpolated straight line joining the absorption values at the isosbestic wavelengths of 526 and 586nm. This, in part compensates for the melanin concentration.

The straightened spectra are normalised by division by the integral of the absorption values from 526 to 586nm.

The algorithm can make use of two reference spectra. These spectra may be from whole blood (measured in a cuvette) or spectra recorded in skin or the mean spectra recorded from several individuals. One reference spectrum is of fully oxygenated haemoglobin the other is of fully deoxygenated haemoglobin. The fully oxygenated spectrum is obtained by equilibration of whole blood in the cuvette with 95% oxygen and 5% CO_2 at 37°C or, in skin of the forefinger heated to 44°C at maximal reactive hyperaemia following release of the inflatable cuff after 6 minutes of brachial artery

occlusion. The fully deoxygenated spectrum is obtained by equilibration of whole blood in the cuvette with 95%N_2 and 5% CO_2 at 37°C or, in skin of the forefinger heated to 44°C at the end of a 6 minute period of brachial artery occlusion prior to release of the inflatable cuff. The reference spectra are K-M transformed, "straightened" and normalised as described above.

An iterative process sequentially "mixes" the two references spectra in increments of 1% until the best least squares fit is achieved with the measured spectrum using all the absorption values at the 22 wavelengths. The iteration typically starts by adding 100 parts of the fully oxygenated spectrum to 0 parts of the fully deoxygenated spectrum, then 99 parts of the fully oxygenated spectrum to 1 part of the fully deoxygenated spectrum and so forth until the sum of the squares of the differences between the measured absorption values and those obtained by combining the reference spectra reaches its minimum value. The resultant SO_2 value is the proportion of the oxygenated reference spectrum in the best fitted spectrum (eg 80 parts of the fully oxygenated spectrum with 20 parts of the fully deoxygenated spectrum would give an SO_2 value of 80%).

A maximum limit on the least squares value is stipulated such that noise or artefacts in the recorded spectra lead to the rejection of the SO_2 value.

A further important aspect of this invention is the fact that our technique measures arterial blood oxygen saturation. This is achieved in the following way: at normal skin temperature an optical measurement made on the skin of a patient would measure the oxygen saturation of a mixture of venous and arterial blood in the capillaries. In our technique we heat the skin below the sensor to below 40°C. The effect of this application of heat is to cause an increase in skin blood flow, sufficient to cause the oxygen saturation of the blood in the capillaries in the skin to equilibrate with the arterial blood supply. In this way the optical device will measure the equivalent of arterial blood oxygen saturation.

According to a further feature of the invention we provide a method of monitoring of SIDS in infants which comprises attaching a calibrated sensor as hereinbefore described to the skin of a patient and emitting white light, detecting and a measuring the scattered light.

According to a further feature of the invention we provide a sensor device which measures SO_2 as hereinbefore described coupled to an oximeter eg a pulse oximeter, which is conventionally known per. The sensor device of this embodiment will measure SO_2, while the pulse oximeter will measure SaO_2, at least intermittently, and allowing the scaling factor Δ to be calculated and intermittently monitored. Thus the sensor device of this embodiment measures SO_2 but displays SaO_2.

Thus according to a yet further feature of the invention we provide a method of SaO_2 monitoring which comprises measuring SO_2 and adding a scaling factor Δ as hereinbefore defined.

The method of the invention preferentially comprises the use of a sensor device of the invention. In the most preferred method, the sensor is used to continually measure SO_2 and to intermittently measure SaO_2 allowing the motion artefact to be annulled.

In a further embodiment, the method of the invention as hereinbefore described includes the use of the Kubelka and Monk transformation to account for melanin levels in skin.

The invention will now be described by way of example only and with reference to the accompanying drawings in which Figure 1 is a schematic representation of the optical measurement method of the invention;

Figures 2(a) and 2(b) are both graphs which illustrate how the SO_2 values are calculated;

Figure 3 is a “hand held” sensor according to the invention;

Figure 4 is a representation of the schematic layout of the optical system of the sensor of the invention;

Figure 5 is a representation of the hand held sensor of the invention in use; and

Figure 6a to d are graphs representing measured SO_2 values for different skin colours.

With reference to Figure 1, an optical blood saturation sensor (1) comprises transmitting fibres (2) from a lamp (not shown) which transmit light to be reflected from a mirror (3) onto the skin (4) of a patient where the light in proportions is absorbed and scattered or reflected depending upon the oxygen content of the haemoglobin and the wavelengths of light used. Reflected light (5) is detected by receiving fibres (6) and transmitted to a photometer (not shown).

The measurement technique can best be understood by reference to Figures 2(a) and 2(b). Analysis of the data to obtain an index of haemoglobin concentration and arterial oxygen saturation (SaO_2) is carried out as follows: the gradients between 5 isobestic wavelengths (500, 520, 548, 575 and 586nm) are added to given an index which is related to the haemoglobin concentration. This index is used to normalise the measured tissue spectra. The oxygen saturation (SO_2) is calculated from the gradients between the absorption peaks for de-oxygenated haemoglobin (560nm) and the two adjacent isobestic wavelengths (548 and 575nm) of the normalised spectra.

The most important factor influencing the stability of the SaO_2 lies in our 6 wavelength analysis technique which incorporates the 5 isobestic wavelengths and the single oxygenated/deoxygenated peak. The two accompanying Figures illustrate how the HbI and SO_2 values are obtained from the spectra. HbI is the sum of the moduli of the slopes of the lines connecting the isobestic points as shown in the first Figure 2(a): it can be seen that any change in the general level of the signal, such as may occur due to small changes in the distance of the probe from the skin would not

have any significant influence on this value. The absorption spectrum may shift up or down, but the sum of the moduli of the slopes remains constant.

SO_2 values (Figure 2(b)) are calculated from the sum of the moduli of the slopes of the extinction values between the neighbouring isobestic points and the deoxygenated peak, normalised to the HbI value. We thus obtain not only an SO_2 value but, on the way, we can also obtain a measure of relative haemoglobin concentration (HbI) from our measurements.

With reference to Figure 3 a hand held sensor (7) may comprise a fibre optic cable (8), a prism (9), an LED (10) and a heater and temperature sensor (11). The sensor (7) is provided with insulation (12).

With reference to Figure 4, a sensor (13) is provided with 6 fibre bundles (14), a light source (15) and a thermistor (16).

CLAIMS

1. A sensor device which comprises light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength of light received by the photodetector means characterised in that the sensor device measured blood oxygen saturation.

2. A sensor device according to Claim 1 characterised in that the sensor a plurality of wavelengths.

3. A sensor device according to Claim 2 characterised in that the sensor uses a spectral wavelength of from 500 to 600 nm.

4. A sensor device according to Claim 3 characterised in that the sensor uses a spectral wavelength of from 526 to 586 nm.

5. A sensor device according to Claim 2 characterised in that the different wavelengths bear a predetermined relationship with each other

6. A sensor device according to Claim 2 characterised in that the sensor uses 3 or more different wavelengths.

7. A sensor device according to Claim 6 characterised in that the number of wavelengths used is 5 or 6.

8. A sensor device according to Claim 2 characterised in that at least one of the wavelengths is an isobestic wavelength.

9. A sensor device according to Claim 8 characterised in that most of the wavelengths are isobestic wavelengths.

10. A sensor device according to Claims 7 or 9 characterised in that five wavelengths are isobestic and one wavelength provides the maximum absorption difference between oxygenated haemoglobin and deoxygenated haemoglobin.

11. A sensor device according to Claim 7 characterised in that the number of wavelengths used are selected from 500, 528, 550, 560, 572 and 586 nm.

12. A sensor device according to Claim 7 characterised in that the scattered light is transmitted along 6 separate fibres to 6 photodetectors via narrow-band optical filters all in the range 500 to 600nm.

13. A sensor device according to Claim 12 characterised in that the optical filters are all in the range 526 and 586 nm.

14. A sensor device according to Claim 7 characterised in that the scattered light is transmitted along a single fibre of from 50 to 150nm in diameter used with one to three white LEDs.

15. A sensor device according to Claim 1 characterised in that it operates on reflectance (remittance).

16. A sensor device according to Claim 1 characterised in that is a "hand held" sensor device.

17. A sensor device according to Claim 1 characterised in that it is coupled to an oximeter.

18. A method of SaO_2 monitoring which comprises measuring SO_2 and adding a scaling factor Δ.

19. A method according to Claim 18 characterised in that the method includes the use of a sensor device of claim 1.

20. A method according to Claim 18 characterised in that the sensor is used to continually measure SO_2 and to intermittently measure SaO_2.

21. A method according to Claim 18 characterised in that the Kubelka and Munk transformation is used to account for melanin levels in skin.

22. A method according to claim 21 characterised in that the method involves the use of an algorithm;

$$\text{K-B Transformed spectrum} = 0.5 \times (R^2)/(1-R)$$

where R is the remitted spectrum,

and which involves the steps of measuring the remitted spectrum from a light source measuring arterial blood flow.

23. A method according to claim 18 characterised in that the method the sensor is normalised against darkness and a standard white surface, and the signal from each photodiode is measured to obtain the overall dark and "white balance" figures.

24. A method according to claim 18 characterised in that signal processing includes averaging for a period between 10 milliseconds to 10 seconds, subtracting the white balance signal, and taking a logarithm to produce a transmittance at each wavelength.

25. A method according to claim 18 characterised in that more than 22 absorption values are recorded within that range 526 to 586nm.

26. A method according to claim 18 characterised in that one reference spectrum is of fully oxygenated haemoglobin the other is of fully deoxygenated haemoglobin.

27. A method of monitoring of SIDS in infants which comprises attaching a calibrated sensor according to claim 1 to the skin of a patient and emitting white light, detecting and a measuring the scattered light.

28. A data collection, processing and display system comprising the parameters of code number protection, sampling parameters, supply air flow rates, chamber pressure, exhaust air flow rates, top timer bar, bottom set-up bar and file identification bar.

29. A computer programme product adapted for absorption data collection, processing and display of SO_2 and SaO_2 levels.

30. A computer programme product according to claim 26 characterised in that the processing includes the use of the algorithm:

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]}$$

SaO_2 is arterial oxygen saturation

wherein the reflected absorptions (A) at six wavelengths (500, 528, 550, 560, 572 and 586 nm) are used to calculate two parameters HbI and OXI:

$$HbI = (A_{528} - A_{520}) + (A_{550} - A_{528}) + (A_{572} - A_{550}) - (A_{586} - A_{572})$$

$$OXI = ((A_{550} - A_{50}O) + (A_{572} - A_{560})) / HbI$$

and

SO_2 is calculated from the formula:

$$SO_2 = 100 = (OXI - OXI_o) / (OXI_{100} - OXI_o)$$

wherein OXI_o and OXI_{100} are empirically determined values for OXI at SO_2 values of 0% and 100% in skin.

31. A sensor device programmed with a computer programme according to claim 26.

32. A sensor device substantially as described with reference to the accompanying examples.

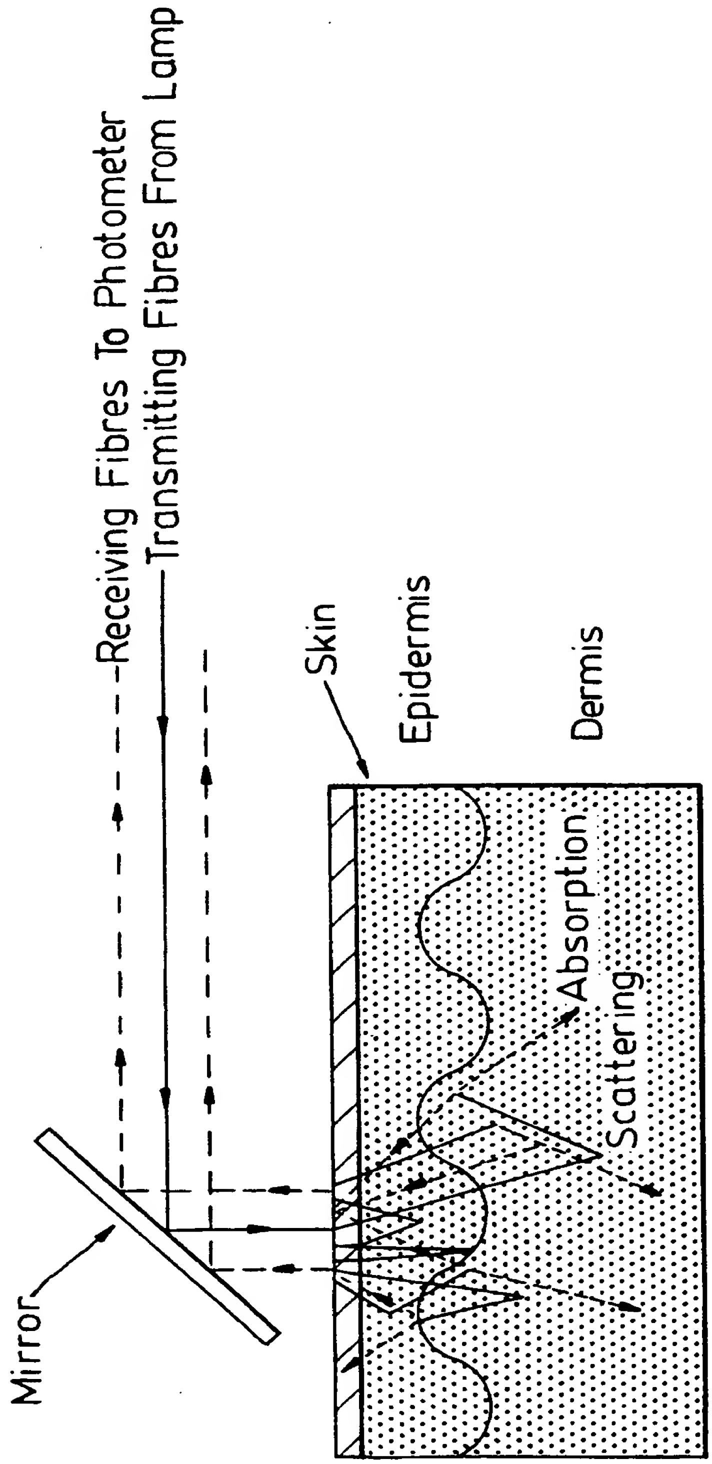
Receiving Fibres To Photometer
Transmitting Fibres From Lamp
Skin
Epidermis
Dermis
Absorption
Scattering
Mirror

Fig. 1

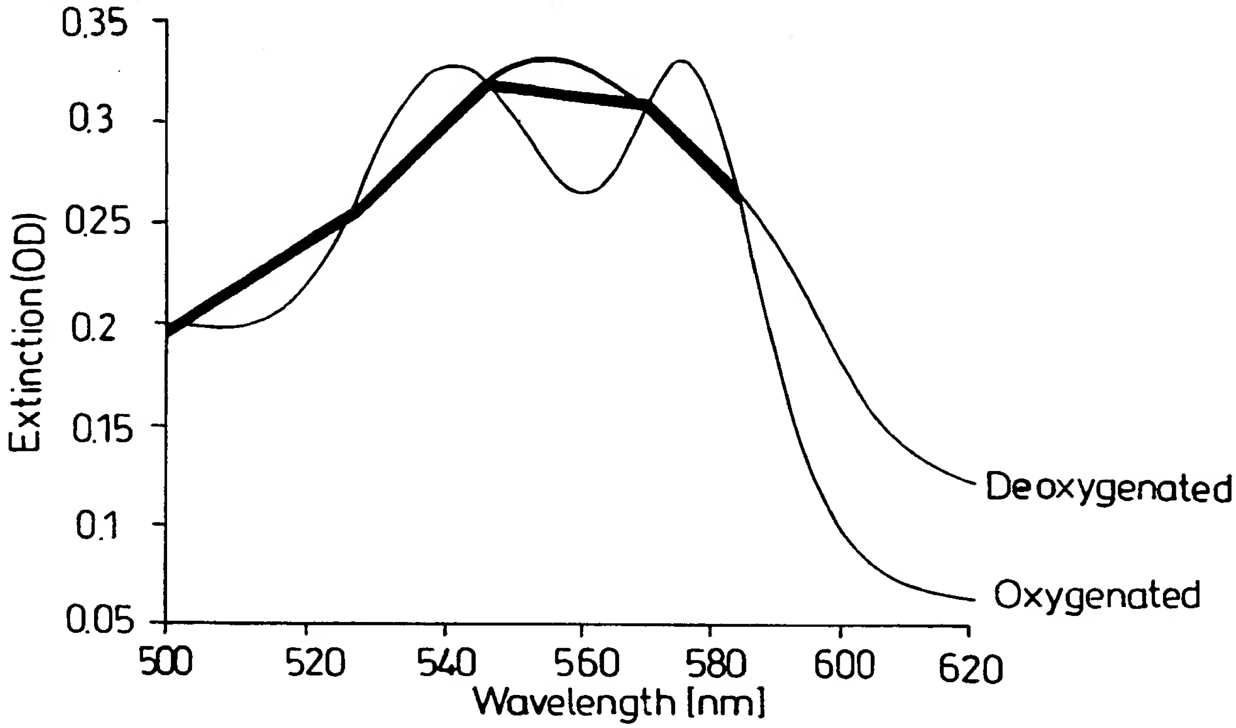
0.35
0.3
0.25
0.2
0.15
0.1
0.05
Extinction (OD)
500
520
540
560
580
600
620
Wavelength [nm]
Deoxygenated
Oxygenated

Fig. 2a

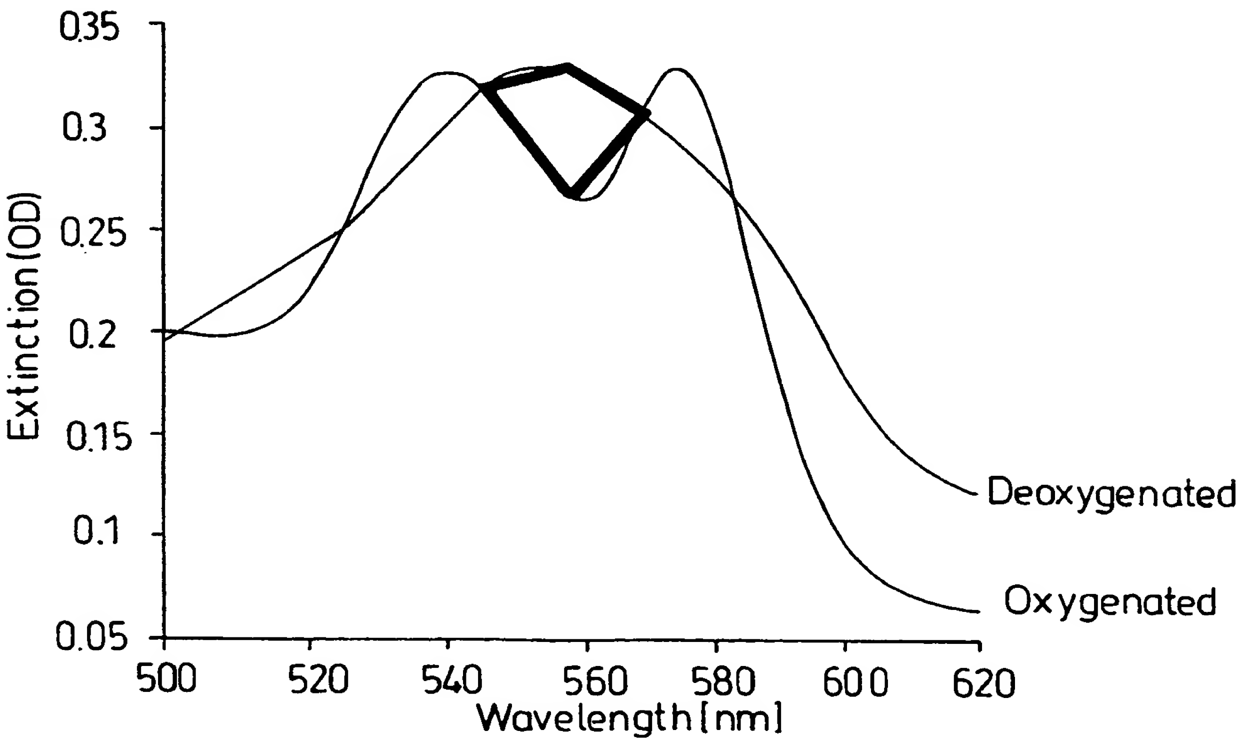
0.35
0.3
0.25
0.2
0.15
0.1
0.05
Extinction (OD)
500
520
540
560
580
600
620
Wavelength [nm]
Deoxygenated
Oxygenated

Fig. 2b

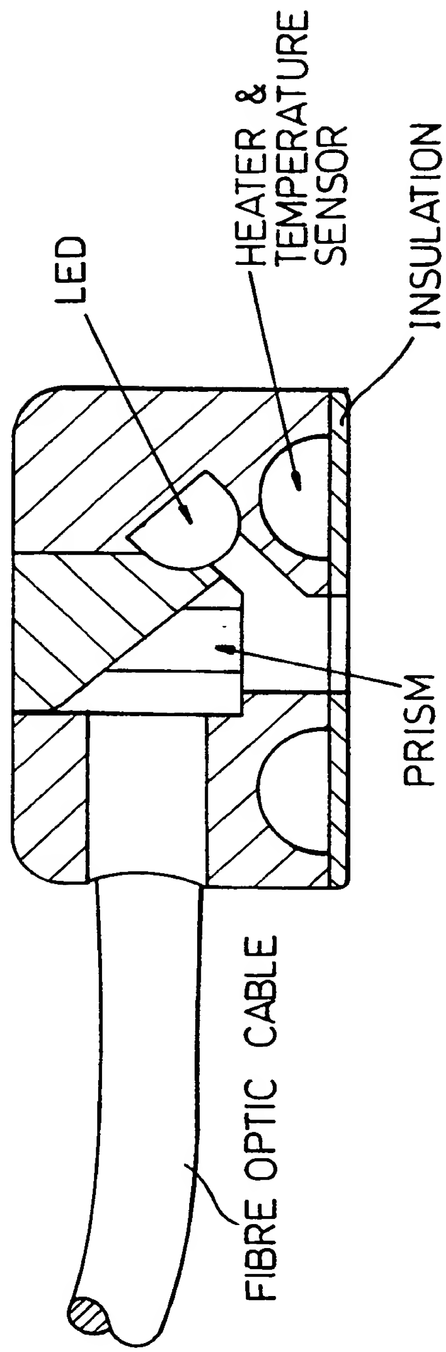
LED
HEATER & TEMPERATURE SENSOR
INSULATION
PRISM
FIBRE OPTIC CABLE

Fig. 3

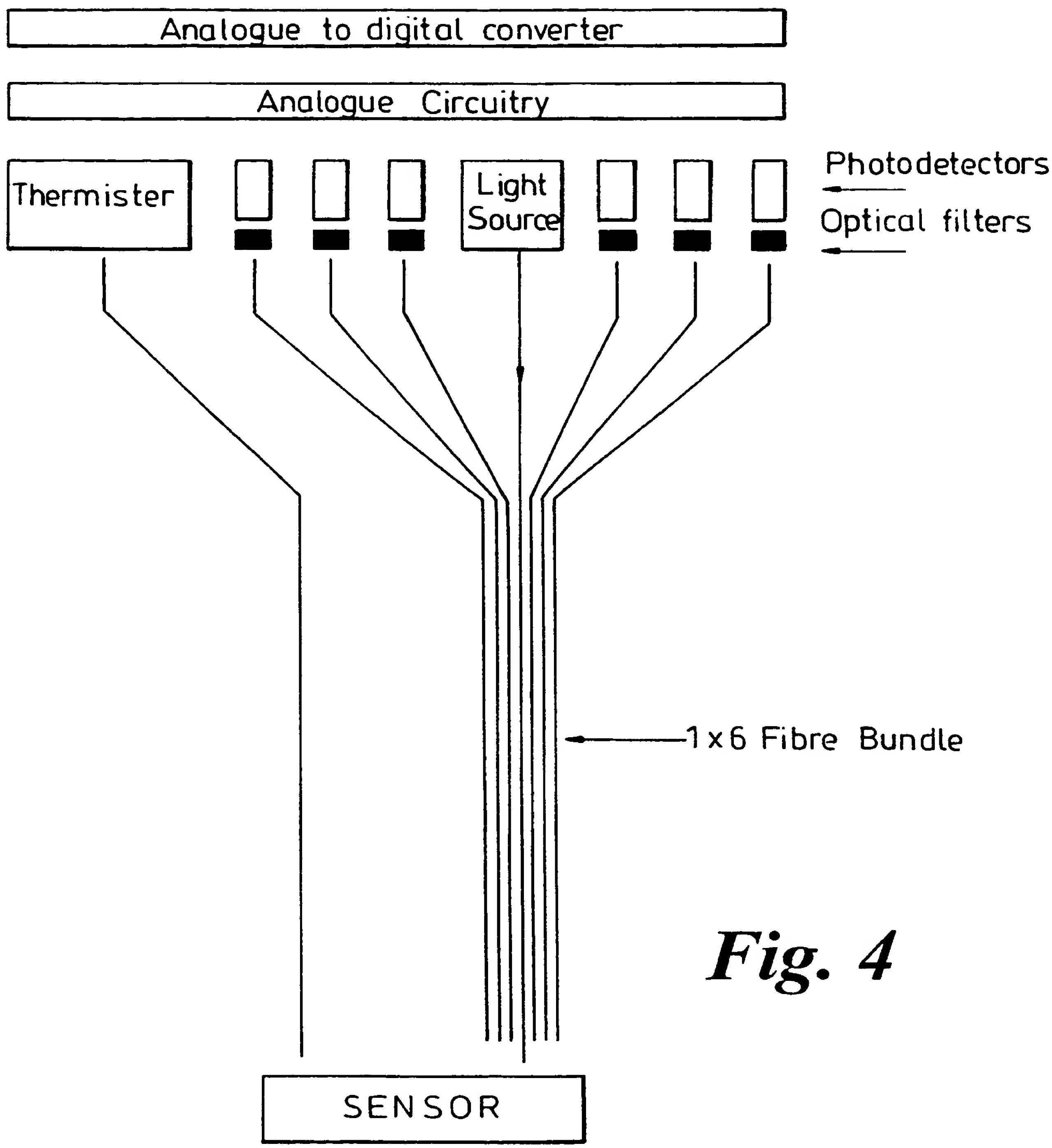
Analogue to digital converter
Analogue Circuitry
Thermister
Light Source
Photodetectors
Optical filters
1x6 Fibre Bundle
SENSOR

Fig. 4

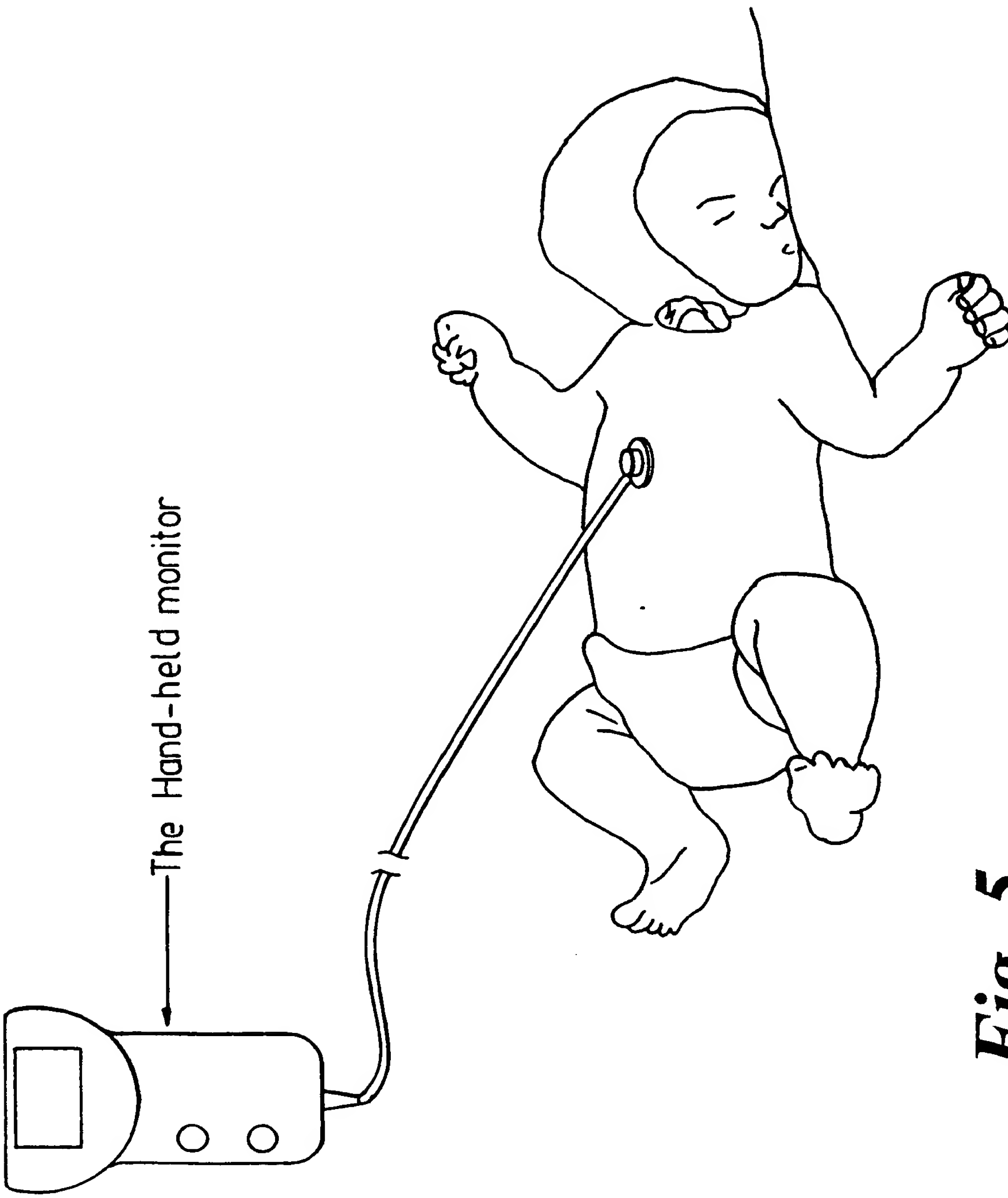

Fig. 5

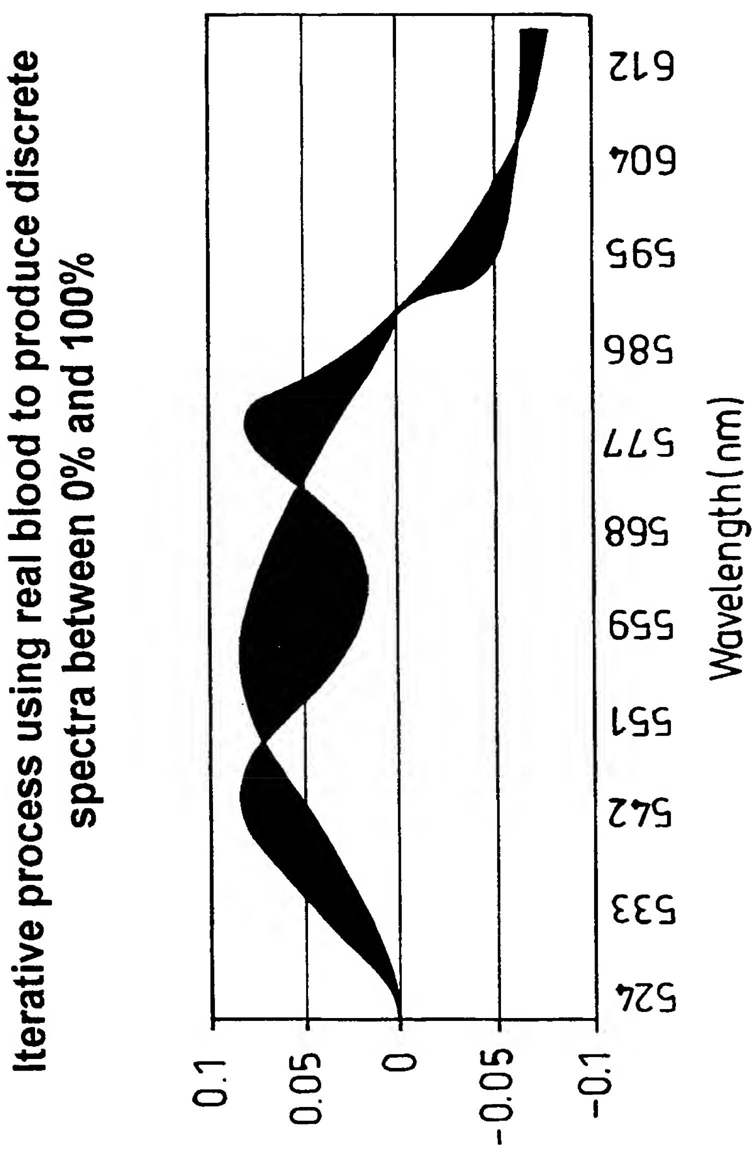
Iterative process using real blood to produce discrete spectra between 0% and 100%
0.1
0.05
0
-0.05
-0.1
524
533
542
551
559
568
577
586
595
604
612
Wavelength (nm)

Fig. 6a

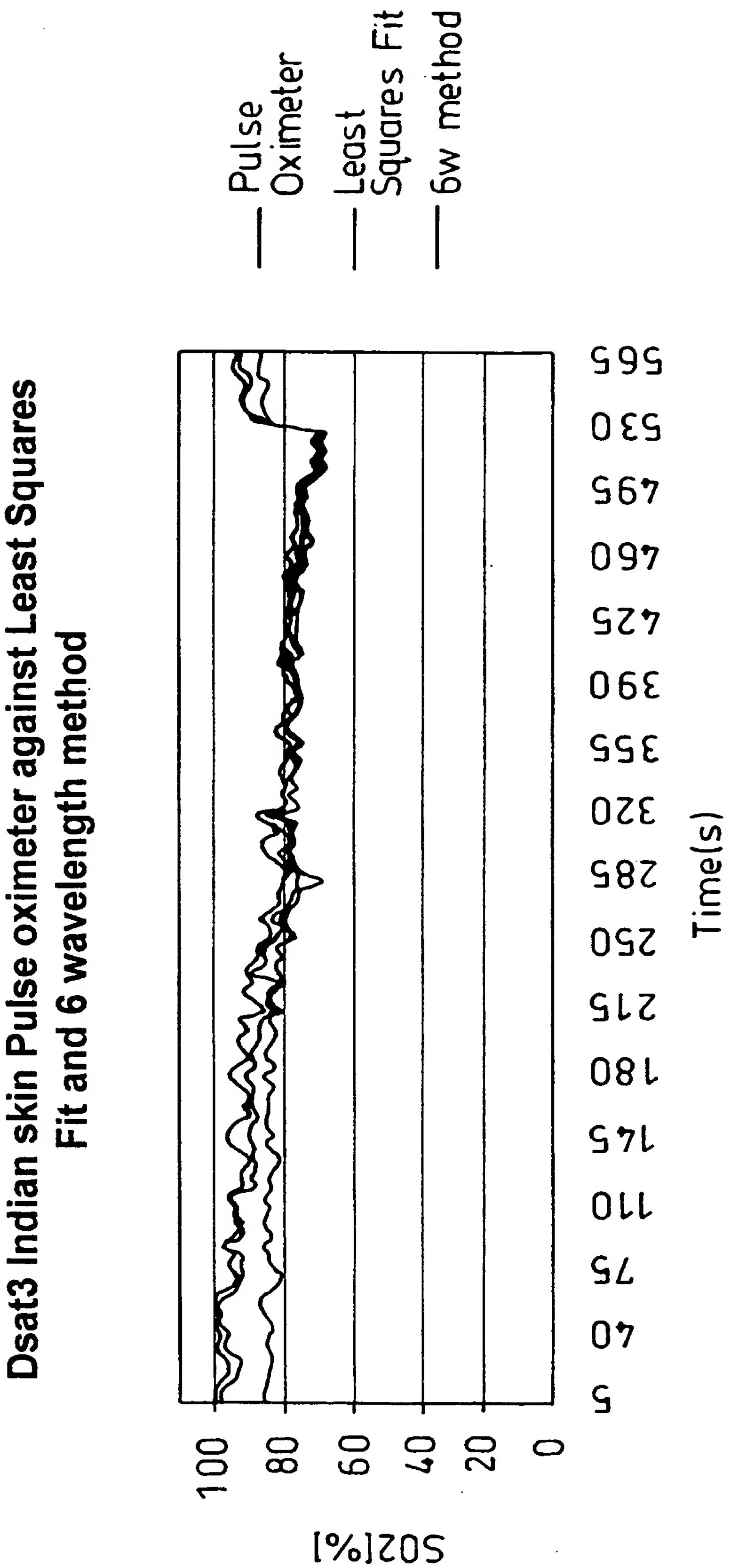
Dsat3 Indian skin Pulse oximeter against Least Squares Fit and 6 wavelength method
Pulse Oximeter
Least Squares Fit
6w method
SO2[%]
100
80
60
40
20
0
5
40
75
110
145
180
215
250
285
320
355
390
425
460
495
530
565
Time(s)

Fig. 6b

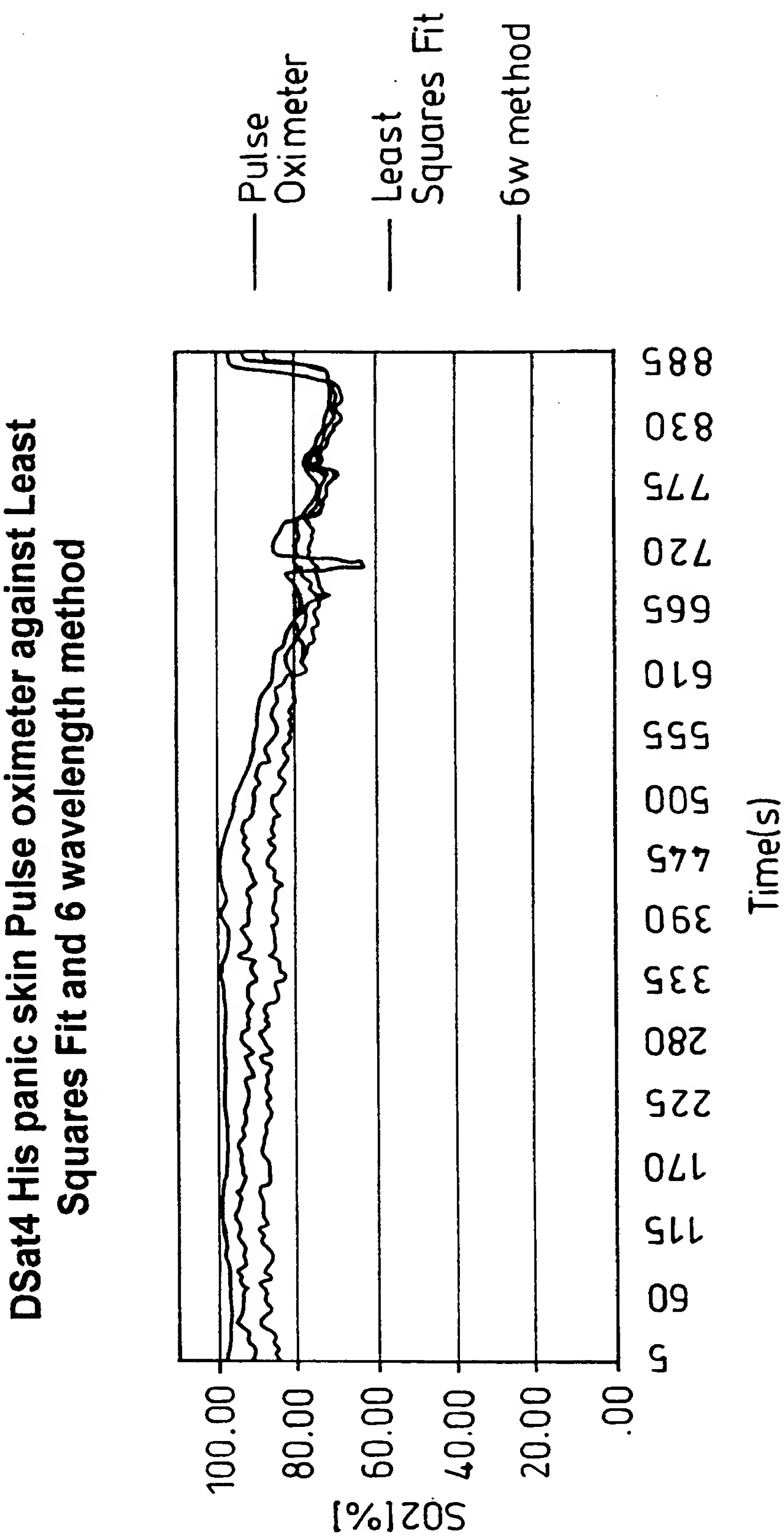
DSat4 His panic skin Pulse oximeter against Least Squares Fit and 6 wavelength method
Pulse Oximeter
Least Squares Fit
6w method
SO2[%]
100.00
80.00
60.00
40.00
20.00
.00
5
60
115
170
225
280
335
390
445
500
555
610
665
720
775
830
885
Time(s)

Fig. 6c

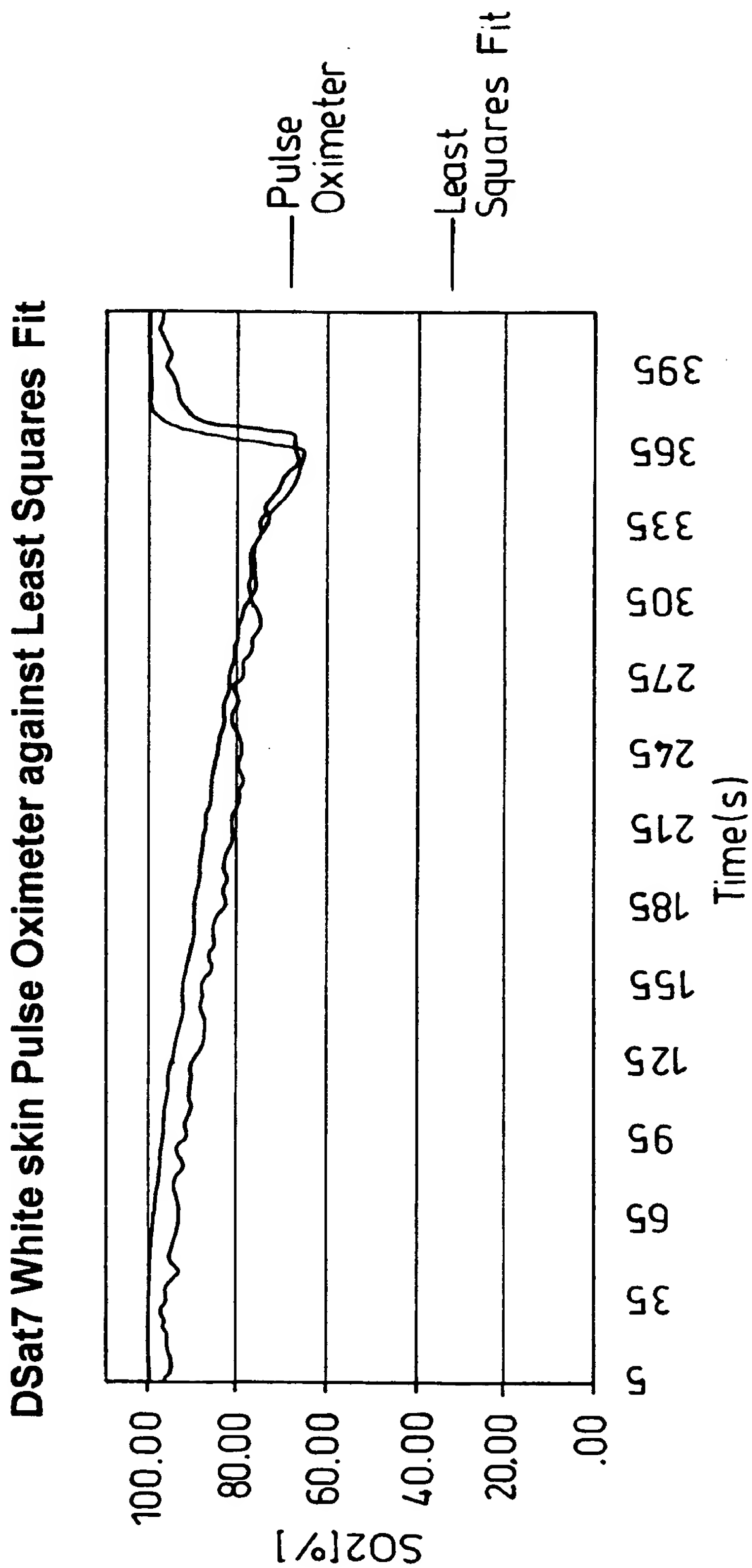
DSat7 White skin Pulse Oximeter against Least Squares Fit
100.00
80.00
60.00
40.00
20.00
.00
SO2[%]
5
35
65
95
125
155
185
215
245
275
305
335
365
395
Time(s)
Pulse Oximeter
Least Squares Fit

Fig. 6d

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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(71) Applicant *(for all designated States except US)*: WHITLAND RESEARCH LIMITED [GB/GB]; Whitland Abbey, Whitland, Dyfed SA34 0LG (GB).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: PARKER, Dawood [GB/GB]; Whitland Abbey, Whitland, Dyfed SA34 0LG (GB).

(74) Agent: GILHOLM, Steve; Harrison Goddard Foote, Belmont House, 20 Wood Lane, Leeds LS6 2AE (GB).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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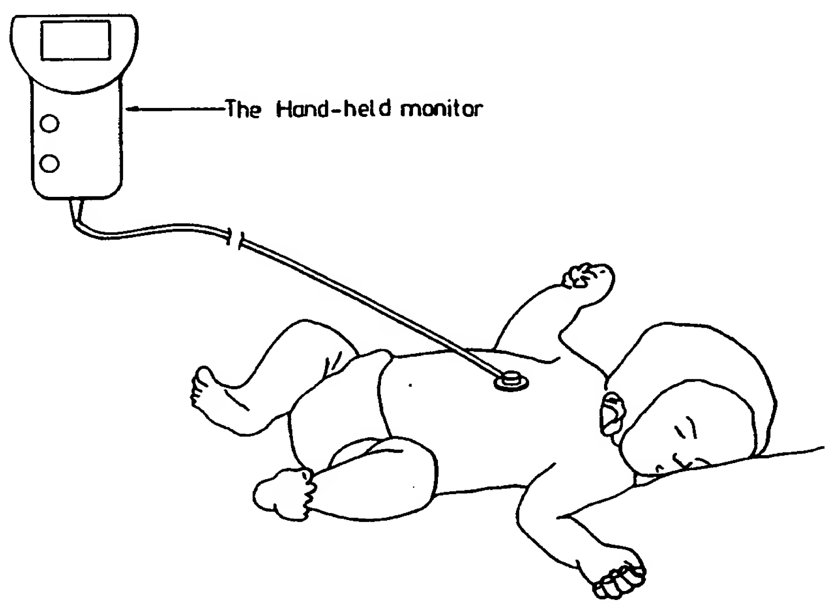
(54) Title: OPTICAL DEVICE



(57) Abstract

A sensor device (1) which comprises light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength f light received by the photodetector means characterised in that the sensor device measures blood oxygen saturation. The device can be used in conjunction with a conventional pulse oximeter. There is also described a method of measuring blood oxygen saturation.

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INTER[illegible]TIONAL SEARCH REPORT

Interna[illegible]al Application No
PCT/GB 99/02510

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 03102 A (UNIVERSITY COLLEGE OF SWANSEA ET AL) 17 February 1994 (1994-02-17) cited in the application page 1, line 28 -page 3, line 8 abstract ---	1,2,5,6, 15,17,32
X	US 3 638 640 A (R. F. SHAW) 1 February 1972 (1972-02-01)	1,2,5,6, 15,32
A	column 2, line 30 -column 3, line 50 ---	7,16,17
X	EP 0 286 142 A (SUMITOMO ELECTRIC INDUSTRIES, LIMITED) 12 October 1988 (1988-10-12)	1,2,5,6, 15,32
Y	page 2, line 13 -page 4, line 4 --- -/--	3,4,7,8

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"P" document published prior to the international filing date but later than the priority date claimed

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 November 1999	22 02 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Geffen, N

1

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 586 025 A (M. R. ROBINSON ET AL) 9 March 1994 (1994-03-09)	1,2,5,6, 15,32
Y	page 4, line 32 - line 54 page 10, line 48 -page 13, line 15	3,4,7,8
A		9-14,17

Y	WO 91 01678 A (NATIONAL RESEARCH DEVELOPMENT CORPORATION) 21 February 1991 (1991-02-21)	3,4
A	page 3, line 6 -page 5, line 4	1,2,5,6, 11-13,32

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 99/02510

B x I Obs rvations where c rtain claims were found uns ar habl (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 29-30
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1 (iv) PCT - Program for computers

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-17,32

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/GB 99/02510

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-17, 32

   A sensor device for measuring blood oxygen saturation.

2. Claims: 18-27

   A method of monitoring arterial blood oxygen saturation comprising measuring blood oxygen saturation and adding a scaling factor.

3. Claim : 28

   A data collection, processing and display system.

4. Claim : 31

   A sensor device programmed with a computer programme adapted for absorption data collection, processing and display of blood oxygen saturation and arterial blood oxygen saturation levels.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 99/02510

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
WO 9403102	A	17-02-1994	AU	4719893	A	03-03-1994
			ZA	9305579	A	02-02-1994
US 3638640	A	01-02-1972	DE	2049716	A	13-04-1972
EP 0286142	A	12-10-1988	JP	63252239	A	19-10-1988
			DE	3851251	D	06-10-1994
			DE	3851251	T	15-12-1994
			US	4867557	A	19-09-1989
EP 0586025	A	09-03-1994	US	5355880	A	18-10-1994
			CA	2099400	A	07-01-1994
			JP	6178767	A	28-06-1994
			US	5630413	A	20-05-1997
			US	5792050	A	11-08-1998
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			GB	2235288	A,B	27-02-1991
			JP	5504266	T	08-07-1993